UNITED STATES DISTRICT COURT, WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ORG Lluch Salvado, S.A.,

Plaintiff,

v.

DENDREON CORPORATION, MITCHELL GOLD, and DAVID URDAL,

Defendants.

No.

COMPLAINT FOR VIOLATIONS OF THE SECURITIES LAWS

JURY TRIAL DEMANDED

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Plaintiff ORG Lluch Salvado, S.A. ("plaintiff"), by and through its counsel, alleges upon personal knowledge regarding itself and as to all other matters based upon the investigation conducted by its attorneys which included, among other things, a review of Securities and Exchange Commission ("SEC") filings, documents from the United States Food and Drug Administration ("FDA"), press releases and media reports of Dendreon Corporation ("Dendreon" or the "Company"), and other publicly available information regarding the Company, as follows:

I. NATURE OF THE ACTION

1. Plaintiff purchased shares of the common stock of Dendreon between March 29, 2007, and May 8, 2007, inclusive ("Relevant Period") and suffered substantial monetary losses as a direct result of the material misrepresentations and omissions alleged herein. Plaintiff's losses are set forth in Exhibit A, which plaintiff incorporates herein by reference. Plaintiff brings claims pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5 promulgated thereunder.

2. Dendreon is a biotechnology company focused on the development and commercialization of therapies for cancer. The Company's flagship product is Provenge (sipuleucel-T), an active cellular immunotherapy for advanced prostate cancer with, according to some analysts, a greater than a billion dollar potential market. Provenge is not a typical drug that is simply introduced into the patient's body. Instead, Provenge is an autologous product, meaning it is derived, in part, from the patient's own blood. White blood cells are extracted and shipped to the Dendreon manufacturing facility where they are processed with a recombinant protein to activate an immune response. A single finished lot of Provenge consists of one small bag (about 250 milliliters) containing a solution of live, processed cells from a single patient. The activated cells are then returned to be infused back into the patient to help stimulate a response to the cancer. The shelf life of both the incoming immune cells and the combined

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product is short; thus, manufacturing, quality control ("QC"), and shipping procedures need to be carefully coordinated.

3. Manufacturing Provenge is largely a manual process. Once a patient's blood cells arrive at Dendreon's facility, processing begins at one of 12 manufacturing workstations. An operator dedicated to the lot manually performs steps to separate the mononuclear cells from other blood cells, suspends those mononuclear cells in a culture medium, and introduces a precise amount of antigen, a substance that when introduced into the body triggers the production of an antibody by the immune system based on the number of mononuclear cells present. This process takes four to five hours, after which the product is bagged and placed in an incubator for 36-44 hours. An operator then manually separates and washes the mononuclear cells, suspends them in a solution, and again bags them – a process which takes approximately two hours. An additional person dedicated to the lot – the "verifier" – then checks the work of the previous two operators. Afterwards, the Company samples the product for various quality-control measures, including sterility, microbial contamination, endotoxin levels, and viability.

4. On November 9, 2006, Dendreon submitted a Biologics License Application ("BLA") for Provenge to the FDA. The FDA granted Priority Review status, meaning that the FDA would reach and announce a decision whether to approve Provenge on or before May 15, 2007 (the "PDUFA" date).

5. As Dendreon has acknowledged in its SEC filings, a critical part of the BLA review process is a Chemistry, Manufacturing & Controls ("CMC") inspection of the Company's manufacturing facility. A CMC inspection is a detailed inspection covering the applicant's manufacturing, training, product testing, support systems, and record-keeping methods. Dendreon could not obtain FDA approval of Provenge and, consequently, could not market Provenge, unless it passed the CMC review.[1]

[1] *See* Public Health Act of 2005, 21 U.S.C. § 251; 21 C.F.R. § 601.2 (BLA approval requires applicant's proposed commercial production facility to be in compliance with current Good Manufacturing Practices ("cGMP")); Dendreon's Form 10-K for the year ended December 31, 2006, filed with the SEC on March 14, 2007

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6. In mid-February 2007, the FDA conducted a CMC inspection of Dendreon's New Jersey manufacturing facilities, and issued to the Company an FDA Form 483, Inspectional Observations Report, detailing nine "significant objectionable conditions" observed at those facilities. The issuance of the Form 483 to Dendreon was a material, adverse event for the Company in light of all of the facts and circumstances of its issuance, including, among other things, the enormous significance to the Company and investors in its stock of obtaining FDA approval to commercialize Provenge by the May 15, 2007 deadline. Defendants knew that until those "significant objectionable conditions" were resolved to the FDA's satisfaction, defendants could not obtain FDA approval of Provenge and, consequently, could not market Provenge. Indeed, Provenge did not ultimately obtain FDA approval until late April 2010, following a second pre-licensing inspection in 2010.[2]

7. While the issuance of a Form 483 after a pre-approval inspection is, by itself, a highly-material adverse event regardless of the number or relative severity of the conditions found to exist, the "significant objectionable conditions" that the FDA cited regarding the Company were severe and numerous. Furthermore, the FDA cited those conditions that had not yet been resolved as the first reason for its rejection of the Provenge BLA in May 2007, as described below.

8. On March 29, 2007, after the FDA's Office of Cellular, Tissue and Gene Therapies Advisory Committee ("Advisory Committee") announced its recommendations that Provenge was both safe and efficacious, Dendreon held a conference call with investors and securities analysts. During that conference call, defendants revealed for the first time that the FDA's pre-license inspection had taken place six weeks earlier. When Dendreon's President and Chief Executive Officer ("CEO"), Mitchell H. Gold ("Gold"), was asked by an analyst whether

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(our facilities "must pass a pre-approval inspection for compliance with the applicable regulations as a condition of FDA approval of *Provenge* or any of our other potential products").

[2] At some point following approval, the FDA posted numerous documents to its Website that had not been made public before, including memoranda documenting communications with Dendreon between November 2006 and May 2010.

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Dendreon's facilities "passed muster," Dendreon's Senior Vice President and Chief Scientific Officer, David R. Urdal ("Urdal"), abruptly interrupted Gold and represented that "we hosted a good inspection," and that "we have ongoing discussions with them between now and between [sic] May 15, to finish the review of the CMC Section." Gold made similar statements with respect to timely completion of the CMC review: "[O]ver the next several weeks we'll be finalizing our discussions with the FDA and we anticipate a decision on Provenge by May 15" and "[r]eally over the next several weeks, we're working on completing our discussions with the FDA and anticipate a decision on Provenge by May 15, 2007."

9. Contrary to Urdal's and Gold's statements, however, when the FDA denied the Provenge BLA filing six weeks later, it became publicly known that the inspection had not, in fact, been a "good inspection," the Form 483 issues placed obstacles in the path of completion of the CMC review process by May 15, 2007 (obstacles that had been neither revealed nor overcome), and that certain of the "significant objectionable conditions" identified by FDA inspectors during that February inspection led the list of reasons for the denial of the Provenge BLA. Indeed, Dendreon later confirmed that it had not completely responded to some of the issues raised by the FDA in the roughly three months from the date of the inspection to the date of the FDA's Complete Response letter ("CR Letter"). Moreover, one of the observations noted during the inspection (Observation No. 1) would require a major amendment to the Provenge BLA. On March 23, 2007, when Dendreon requested that the FDA grant limited approval instead so as to retain the May 15, 2007, review completion date, the FDA indicated that it could not consent to the request without internal discussions and that further discussion of the request would not occur until after the March 29, 2007, Advisory Committee meeting. Investors were not made aware of any of these facts.

10. On March 30, 2007, the day after the analyst conference call, investors, including plaintiff, bought numerous of shares of Dendreon on very heavy trading volume and the price of Dendreon common stock skyrocketed 343%.

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11. On April 2, 2007, just two days before a teleconference with the FDA to discuss the adequacy of Dendreon's response to the Form 483 generally (and whether a major amendment would be required in conjunction with Observation No. 1 specifically), Gold sold 24% of his holdings in Dendreon for approximately $2.7 million dollars. This was Gold's first sale of Dendreon stock.

12. On April 4, 2007, defendant Urdal and other Dendreon representatives participated on a conference call with the FDA to discuss Dendreon's response to the Form 483. While six of the nine observations were either resolved, or soon could be, additional information was requested on two observations and, with respect to Observation No. 1 – which could trigger a delay of the May 15, 2007, review completion date – Dendreon responded to the FDA's proposal by requesting a modification and the opportunity to submit further information in support. The FDA thought Dendreon's request to be "problematic" but agreed to consider the request.

13. Ultimately, the CMC Review was not in Dendreon's favor. FDA inspectors noted that because "some questions remain regarding validation of assays and product stability and quality," "several product manufacturing and control items need to be resolved before assurance of safety, identity, purity and potency of the product is reached."

14. On May 8, 2007, the FDA issued its Complete Response letter to Dendreon, rejecting the application to approve Provenge. In doing so, the FDA cited the CMC issues with the inspection as the first reason for denying approval to Provenge. The market price of Dendreon's stock immediately plummeted from $17.74 to $6.33 per share when defendants announced receipt of the FDA's decision the following day.

15. In a May 10, 2007 conference call with securities analysts and investors, defendants for the first time acknowledged that a Form 483 had been issued in February 2007, that the FDA inspectors had then identified multiple "significant objectionable conditions," and that Dendreon had not completed its response to some of them. Defendants disingenuously

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stated that Dendreon had "very little, if any" substantive discussions with the FDA after the March 29, 2007, Advisory Committee meeting regarding those issues. When pressed for "a sense of the number of observations or what kind of observations that have been noted," Gold asserted that they were "proprietary to the Company." Notwithstanding defendants' refusal to disclose the Form 483, even in redacted form, circumstantial evidence made clear to investors at the time that the problems cited therein were severe:

- The Form 483 was issued in the middle of February 2007. On May 8, 2007, the FDA denied the BLA for Provenge, citing in its CR Letter that the Form 483 issues remained unresolved. Thus, Dendreon had apparently been unable to resolve certain issues for roughly three months;

- On May 10, 2007, Urdal confirmed that the CMC issues cited in the FDA's CR Letter were the same as those cited in the Form 483 and that Dendreon had not completed its response to all of the issues;

- Rather than disclosing the significant objectionable conditions that the inspectors found and informing investors that they believed they could be resolved by May 15, 2007, defendants concealed the issuance of the Form 483 until the FDA issued its CR Letter; and

- As of March 13, 2008, nearly one year later, defendants were still unable to confirm that they had responded to all of the problems observed in February 2007, stating that Dendreon had "substantially responded to" the CMC issues.

16. In light of these facts, Urdal's March 29, 2007, statement that Dendreon "hosted a good inspection" was both objectively and subjectively false and misleading when made. Urdal could not have reasonably believed that the February 2007 inspection – which resulted in a Form 483 with nine separate observations, some of which ultimately resulted in denial of FDA approval – was a "good inspection." Urdal, therefore, misrepresented material facts when he stated that Dendreon had "hosted a good inspection." Urdal also knew that this statement – regardless of whether he believed it – would mislead investors regarding the outcome of the inspection, particularly in light of the context it was made (*i.e.*, in response to a question that, in substance and effect, asked whether Dendreon had passed the inspection), and in light of his

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deliberate omission of any mention of the issuance of the Form 483 or the problems identified therein, including one observation that could require a major amendment to the BLA that would preclude approval by May 15, 2007. The remainder of Urdal's statement, that Dendreon was working with the FDA to "finish" the CMC review process by May 15, 2007, was materially misleading for the same reason. Gold's statements regarding the CMC review process were also materially misleading for the same reason. The Individual Defendants' statements, therefore, were intended to calm investor concerns that the inspection itself had presented any roadblocks to Provenge's approval and to conceal the fact that serious open items remained, at least one of which could delay the May 15, 2007, review completion date. Gold and Urdal, who were present when each others' statements were made, similarly knew that the statements were intended to, and would, mislead investors, and yet they made no effort to correct the statements.

17. Accordingly, defendants are liable under the Exchange Act for falsely representing that Dendreon "hosted a good inspection" when they knew such was not the case and for materially misleading investors about completion of the CMC process by May 15, 2007. Gold and Urdal are also liable as controlling persons of Dendreon under Section 20(a) of the Exchange Act. Defendants' fraudulent acts caused the price of Dendreon's stock during the Relevant Period to be artificially inflated, resulting in substantial damage to plaintiff.

II. JURISDICTION AND VENUE

18. These claims arise under, and pursuant to, Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. §§ 240.10b-5. Jurisdiction is conferred by, and venue is proper pursuant to, Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331. Many of the acts and transactions giving rise to the violations of law complained of herein, including the preparation and dissemination of materially misleading statements, occurred in this judicial district. In addition, Dendreon maintains its principal executive offices in this district at 3005 First Avenue, Seattle, Washington. In connection with the acts, transactions and conduct alleged herein, defendants

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used the means and instrumentalities of interstate commerce, including the United States mails, interstate telephone communications and the facilities of a national securities market.

III. THE PARTIES

19. Plaintiff ORG Lluch Salvado, S.A., is a Spanish company incorporated under the laws of Spain that purchases and sells assets and shares. At the date of its incorporation, ORG Lluch Salvado, S.A., was located at Avenida Francesc Macià, number 60, 13th Floor, in Sabadell, Barcelona, Spain. Plaintiff purchased millions of dollars worth of Dendreon common stock during the Relevant Period, as detailed in Exhibit A, and suffered damages as a result of the violations of the federal securities laws alleged herein.

20. Defendant Dendreon is a Delaware corporation, which maintains its principal executive offices at 3005 First Avenue, Seattle, Washington 98121. Dendreon is a biotechnology company focused on the discovery, development and commercialization of novel therapeutics that harness the immune system. Dendreon's common stock trades on the NASDAQ National Market System under the symbol "DNDN."

21. Defendant Gold is, and at all relevant times was, the President and CEO of the Company. Gold has been Dendreon's CEO since January 1, 2003, and has been a director since May 2002. Gold previously served as the Company's Vice President of Business Development and as Chief Business Officer. Additionally, Gold previously served as the Vice President of Business Development and Vice President of Sales and Marketing for Data Critical Corporation, a company engaged in wireless transmission of critical healthcare data, now a division of GE Medical. Gold was also the President, CEO, and co-founder of Elixis Corporation, a medical information systems company.

22. Defendant Urdal is, and at all relevant times herein was, Dendreon's Senior Vice President and Chief Scientific Officer. Urdal has served as Dendreon's Chief Scientific Officer since joining the Company in 1995. Urdal assumed the position of Senior Vice President in June 2004. In January 2006, Urdal assumed oversight of manufacturing operations for the Company.

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Urdal previously held various positions with Immunex Corporation, including the president of Immunex Manufacturing Corporation, vice president and director of development and head of the departments of biochemistry and membrane biochemistry.

23. Defendants Dendreon, Gold, and Urdal are referred to herein collectively as "defendants." Defendants Gold and Urdal are referred to herein collectively as the "Individual Defendants."

24. The Individual Defendants participated in the day-to-day management of Dendreon and in various of the Company's communications with the FDA. Because of their positions of control and authority with the Company, Gold and Urdal possessed the power and authority to control the contents of Dendreon's annual and quarterly reports, press releases and presentations to securities analysts, money and investment portfolio managers, institutional investors, and the investing public generally, and exercised such power and authority to do so. Because of the management positions of the Individual Defendants and their access to material non-public information, they knew that the adverse facts alleged herein had not been disclosed to, and were being concealed from, the investing public and that defendants' positive representations were materially false and misleading. Moreover, the Individual Defendants, by reason of their management positions and ability to make public statements on behalf of Dendreon, were and are controlling persons, and had the power and influence to cause, and did cause, the Company to engage in the conduct complained of herein. By reason of their position with the Company, the Individual Defendants had access to internal Company documents, reports, and other information regarding the Company's operations and future prospects, and attended management and/or board of director meetings. The Individual Defendants were responsible for the truthfulness and accuracy of the Company's public statements and had a duty to correct any public statements that were, or became, false or misleading. As a result, the Individual Defendants are liable as direct participants in the wrongdoing alleged herein. Defendants Gold and Urdal each made misleading statements to investors, as discussed herein.

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Both failed to correct each other's misleading statements, that were made when both were present and which each knew to be false and misleading at the time.

25. In addition, defendant Gold personally and unjustly profited by trading in Dendreon common stock during the Relevant Period without disclosing material non-public information.

IV. FACTUAL ALLEGATIONS

26. Dendreon is a biotechnology company focused on the development and commercialization of therapies for cancer. Its flagship product is Provenge (sipuleucel-T), an active cellular immunotherapy for advanced prostate cancer. Prostate cancer is the most prevalent non-skin cancer in the United States, with approximately 234,500 new cases diagnosed every year. Provenge is widely viewed as a revolutionary treatment for the treatment of asymptomatic, metastatic, androgen-independent prostate cancer. Dendreon began its first Phase 3 clinical study (D9901) in 2001 and its second Phase 3 clinical study (D9902A) in 2002. The integrated results of these studies showed a median survival benefit of 4.3 months, which is almost double the survival benefit of Taxotere, the most commonly used chemotherapy drug for advanced prostate cancer. Analysts estimated that Provenge could generate as much as $1 billion a year in United States sales once the FDA approved it.

27. In January 2006, Dendreon's cash reserves were dwindling, and the Company had limited options to raise funds from investors. At the time, the Company's stock price hovered around $5.85 per share, down from above $16 per share two years earlier. Additionally, Dendreon had approximately $82 million of cash and cash equivalents – which roughly amounted to the Company's "burn rate" for the prior year. As a result of the Company's financial condition, defendants embarked upon a strategy to seek expedited approval of its BLA for Provenge. Indeed, during a September 2006 conference call, CEO Gold declared that "[a]ll the company's resources currently are focused on the commercialization and eventual approval of Provenge."

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28. On November 9, 2006, Dendreon completed its submission of a BLA for Provenge. The BLA was accepted by the FDA on January 12, 2007, and granted priority review. Pursuant to Prescription Drug User Fee Act III ("PDUFA"), which sets forth timetables for the review of BLA applications, the anticipated date for the FDA's completion of review of Provenge was May 15, 2007. This date is commonly referred to as the "PDUFA date," or the "Complete Response date." By that date, the FDA issues a Complete Response to the application. The period between the FDA's official acceptance date of the BLA, November 15, 2006 and May 15, 2007, is referred to as the "review cycle." The review cycle is six months where, as in the case of the Provenge BLA, the FDA gives Priority Review status to an application.

29. Defendants sought to produce Provenge at a single location – a newly-constructed manufacturing plant in New Jersey. In 2006, Dendreon began building the New Jersey facility under Urdal's oversight on an extremely short timeline. According to Andy Scherer, Dendreon's Vice President of Manufacturing, "[i]n the Biotech industry a new manufacturing facility requires a minimum of 18-24 months to over 5 years from design start to PAI [pre-approval inspection] depending on the size and complexity." In contrast, defendants sought to complete this process for the New Jersey facility in less than 13 months. As a result, Dendreon cut corners to meet "new budget and timeline requirements," deciding "it was necessary to … make compromises in areas of the facility that were deemed non-critical to licensure." Additionally, construction delays further compressed the time available for validation procedures and other preparations. The available time frame for validation was incredibly small; validation activities were delayed because the New Jersey facility was not ready because of the Company's overly-optimistic timelines. As a result, although the Company submitted the clinical portion of its BLA in August 2006, it was unable to submit the CMC section until November 2006.

30. A critical part of the BLA review process is a CMC inspection of the manufacturing facility. A CMC inspection is a highly detailed and rigorous inspection, covering

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the applicant's manufacturing, training, product testing, support systems, and record-keeping methods. The CMC inspection is a very critical step for the start-up of production operations of biotechnology companies, such as Dendreon, that do not have any pre-existing FDA approved products or manufacturing operations, and where rapid growth in the number of production personnel and production equipment and facilities can be anticipated after marketing approval is granted by the FDA. It was even more critical with respect to Provenge, because of the unique manner in which the active component was to be mixed with a patient's own immune cells, which had been sent to Dendreon's manufacturing facility, and then shipped back to the patient.

31. The FDA required the New Jersey facility to pass a pre-approval inspection ("PAI") before approval of Provenge. A PAI is an in-depth audit during which the FDA reviews the applicant's systems to ensure that it can consistently and safely produce an effective product. Both Gold and Urdal were aware of the importance of the PAI – they described the process as an "important event for the company" and "one of the key elements of the approval process." In December 2006, the FDA notified Dendreon that it would begin the PAI on February 12, 2007.

32. A BLA cannot be approved, and a product cannot be marketed, until the applicant demonstrates that its facilities are in compliance with the FDA's cGMP.[3] If the FDA inspector or team observes CMC deficiencies during an inspection, the FDA will issue a Form 483, Inspectional Observations, which is an onsite inspection report identifying those deficiencies. The Form 483 is given to the Company at the conclusion of the inspection and prior to the departure of the inspectors from the facility.

33. A Form 483 lists only "significant objectionable conditions" in a Company's manufacture of an FDA-regulated product. As explained in the FDA Investigations Operations Manual:

> The FORM FDA 483 INSPECTIONAL OBSERVATIONS is intended for use in notifying the inspected establishment's top

[3] *See* Public Health Act of 2005, 21 U.S.C. § 251; 21 C.F.R. 601.2 (BLA approval requires applicant's proposed commercial production facility to be in compliance with current Good Manufacturing Practices (cGMP)).

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> management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts which were observed during the inspection…. Observations which are listed should be significant and correlate to regulated products or processes being inspected.

34. Observations of questionable significance are not included in Form 483s. As stated in the FDA Investigations Operations Manual:

> Observations of questionable significance should not be listed on the FDA-483, but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation.

35. Forms 483s are issued in the course of both pre-approval inspections and post-approval surveillance inspections. In the context of a post-approval inspection, a failure to correct conditions observed in a Form 483 may result in an FDA Warning Letter or other action. In the context of a pre-approval inspection, a failure to correct conditions observed in a Form 483 will result in rejection of the drug application. As a high-level FDA official has explained in public testimony given to Congress:

> The possible outcomes of a surveillance inspection can be much different than a pre-approval inspection. If FDA discovers manufacturing deficiencies while conducting a pre-approval inspection, a possible outcome is that the application or manufacturing supplement may not be approved. If FDA conducts a surveillance inspection and finds deficiencies in the manufacture of products that are currently being marketed, there is a whole range of potential regulatory actions that may occur. These actions include issuing a warning letter or notice of intent to revoke a license, suspending or revoking a license, filing an injunction against the firm or seizure of product.[4]

36. The issuance of a Form 483 during a pre-approval inspection will postpone the applicant's PDUFA date in many cases. Although the applicant may immediately begin taking corrective action upon receipt of the Form 483 and notify the FDA of that action, that corrective

[4] *See* Statement of Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Food and Drug Administration, Before the Committee on Armed Services, United States Senate, July 12, 2000, at 11 ("Zoon Statement"), available at http://armed-services.senate.gov/statemnt/2000/000712kz.pdf

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action has to be approved by the FDA prior to the PDUFA date or the FDA will issue a CR Letter denying the BLA, and the applicant will have to resubmit the BLA.5

37. During this process, if the problem is very minor – a Class One resubmission – the PDUFA date will be postponed approximately two months from the time the FDA accepts a written corrective action plan submitted by an applicant. If the problem requires re-inspection (as could be expected for objectionable conditions involving training, record keeping, ongoing calibrations and maintenance of sterile facilities in a new production facility) – a Class Two resubmission – the PDUFA date will be (initially) postponed by one review cycle, *i.e.*, six months, after the corrective action plan is accepted.

38. The speed of obtaining FDA approval is critical for biotechnology companies such as Dendreon. As Dendreon's Annual Report on Form 10-K for its year ended December 31, 2005, filed with the SEC on March 14, 2006 (the "2005 Form 10-K"), observes, "any delay in obtaining, or inability to obtain, FDA approval of any of our product candidates could materially harm our business and cause our stock price to decline."

39. A CMC inspection is a major hurdle in the BLA process. The issuance of a Form 483 during a pre-approval inspection can delay the market entry of a drug indefinitely. Accordingly, the issuance of a Form 483 is a material fact, and the disclosure that a Form 483 has been issued can have a dramatic adverse impact on the market price of a biotechnology company's stock. For example, another biotechnology company, Discovery Laboratories, saw its price immediately drop over 20% when it was announced in February 2005 that the FDA issued a Form 483 to the manufacturing firm retained by Discovery Laboratories to manufacture its product less than a month before the PDUFA date.

[5] *See* Zoon Statement at 17 ("If the corrective actions appear to be inadequate or have not been implemented prior to the end of the review cycle, or if FDA determines that a follow-up inspection is necessary to verify the corrective actions, FDA will send a complete response letter to the sponsor, which means that the application is not approved. The sponsor, again, may submit information to FDA to start another review cycle.").

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40. The Individual Defendants were well aware of the significance of CMC inspections and the inability to gain approval for Provenge until Dendreon's facilities were brought into compliance with the FDA's cGMP. For example, the Company's 2005 Form 10-K, states:

> Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured (including both those of the sponsor and any third party component manufacturers) and *will not approve* the product unless the manufacturing facilities are in compliance with FDA's cGMP, which are regulations that govern the manufacture, holding and distribution of a product.

41. Additionally, under the "Risks Related to Regulation of our Industry" section of the Company's 2005 Form 10-K, it expressly notes that "[t]he FDA can delay, limit or withhold approval of a product candidate for many reasons, including … the FDA may not approve our manufacturing processed or facilities or the processes or facilities of our collaborators or contract manufacturers." Thus, the disclosure of the issuance of a Form 483 during or before the Relevant Period would have had a dramatic adverse impact on Dendreon's stock price.

42. On December 14, 2006, Dendreon and the FDA agreed that the pre-license inspection of the Company's manufacturing facilities would commence on February 12, 2007. On January 24, 2007, Dendreon contacted the FDA to discuss the manufacturing schedule and to request a list of the documents needed for review on the first day of the inspection. On February 1, 2007, the FDA provided Dendreon with a list of the information it wanted to be available during the inspection.

43. Defendants began preparing for the inspection many months in advance, long before the inspection date was scheduled. Dendreon hired regulatory consultants to conduct mock audits to identify problems at the New Jersey facility. The first mock audit was conducted in August 2006, and resulted in 45 "action items." A second mock audit was conducted in October 2006, and identified 20 issues that "could appear on an FDA Form 483." After the second mock audit, Cyril Possa ("Possa"), Dendreon's Director of Validation, declined to

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participate in a set of PAI meetings, stating that "I feel that we already have more than we can handle from all the audit findings."

44. In its last mock audit during the week of January 15, 2007, the Company fared very poorly. The list of issues from the audit included: (1) "not enough staff" in a variety of positions, including "[m]anufacturing operators;" (2) "lack of experience" in a variety of positions, including "[m]anufacturing and [q]uality operators;" (3) "insufficient equipment" in a variety of areas, including "QC analytical instruments;" (4) "[m]any procedures lacking" for a variety of functions, including "QC samples hold times and conditions;" (5) "[e]xisting procedures not followed" for a variety of functions, including "QC data entered into wrong batch record;" and (6) "[l]ack of adequate controls to provide for safety and quality of product," including "[p]otential [for] product mix-up." Referring to these observations, Mike Hartely, Dendreon's Validation Supervisor, commented to Possa: "I am sure that there is a lot of CYA going on this week."

45. During the week of February 12, 2007, five inspectors from the FDA's Center for Biologics Evaluation and Review inspected Dendreon's manufacturing facilities in New Jersey. Urdal was on-site personally and kept CEO Gold informed by telephone and e-mail. According to Urdal, Dendreon was "focused like a laser" on the inspection and, according to Gold, a "significant portion of the company's resources were focused on hosting an inspection." At the Company's headquarters in Seattle, there were daily, all-company meetings in an auditorium where employees received updates on the inspection.

46. The inspectors found various "significant objectionable conditions" at Dendreon's New Jersey facility. The inspectors expressed particular concern about whether the facility could handle operating at capacity beyond a demonstration level because they observed the Company processing only two lots of Provenge, although the facility had 12 workstations and Dendreon's BLA described concurrent processing using all the workstations. The Company's workstations were in two modules – each containing six workstatations – and Dendreon did not have one of

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the modules in use during the inspection. As a result, the FDA inspectors noted that the "FDA usually sees a facility at full capacity to be able to comment on its functionality – how can FDA be comfortable now?" The inspectors also observed that the quality control laboratory was at a bottleneck at higher volumes and specifically noted that "the QC Lab can cause a bottle-neck in the process. Computer systems, logistics, and planning are not well-linked to everything else. The challenge here is not the complexity of the product, but it is the clocks. All steps are time-limited." The inspectors also expressed concern that any issues in the manufacturing would mean that a cancer patient may not get his or her product back.

47. During the PAI, inspectors also found that the Company's use of Seattle-based headquarters employees and local contractors to supplement facility staff during demonstrations was problematic, stating that "if Provenge is approved Dendreon will not have enough staff fast enough to fulfill manufacturing needs in NJ plant." FDA inspectors also expressed concern about the potential for mix-ups in Dendreon's quality-control laboratory. Maintaining the chain of identity in the quality control laboratory is important because of the risks associated with potential mix-ups. Instead of using a computerized system using barcodes, however, Dendreon relied upon staff members who visually compared lot numbers on samples with the lot numbers on paperwork in an attempt to maintain a chain of identity. FDA inspectors made note of this problem: "Handwritten paper work a source of potential errors – need to have bar coding."

48. As a result, on February 16, 2007, the FDA inspectors issued a Form 483 to the Company upon the conclusion of the inspection. The Form 483 listed nine observations, including several with multiple subparts. According to the FDA's Investigation Operations Manual, a Form 483 is intended for use in notifying the inspected establishment's top management in writing of "significant objectionable conditions." The Form 483 that Dendreon received stated that the observations related to "objectionable conditions and practices." The FDA's Investigation Operational Manual also states that inspectors should rank the significant objectionable conditions in order of significance, with the most important items listed first.

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49. The first three items listed on the Company's Form 483 reflect the notes taken by the FDA inspectors during the inspection. Observation 1 reflected the FDA's concern about Dendreon's operating capacity:

> 1. There are no data to support the concurrent manufacturing of six lots within a clean room module. Process Validation Report QVD No. 50999 includes data from only one day of concurrent manufacturing of three lots in Module 1 and two lots from a second day. The commercial process as described in the Biologics License Application (BLA) specifies the use of two clean room modules, total of 12 workstations, one lot per station.

50. Observation 2 expressed the FDA's concerns with untrained employees and inadequate staffing levels:

> 2. Insufficient personnel from the New Jersey manufacturing site were available to perform Aseptic Process Validation in Module 1 (QVD No. 51000). A New Jersey contract employee with no previous training in aseptic operations gowned in to participate in the aseptic simulation to support this validation study.

51. Observation 3 highlighted Dendreon's deficiencies in its chain of identity in the quality control laboratory:

> 3. The quality control laboratory did not demonstrate adequate ability to maintain the chain of identity for the autologous product.
>
> a. No documented system is in place to track and manage the low of the samples. There is also an inconsistent labeling system to maintain the chain of identity of the samples.
>
> b. The commercial system as described in the BLA and presented during inspection specifies the use of a bar code to maintain identity. The QC laboratory does not have the capacity to read the barcode, nor is it connected to the Oracle database used throughout the rest of manufacturing. In addition, information sent from the QC laboratory to the manufacturing module does not contain a bar code.

52. As discussed above, for a new biotechnology company seeking its first FDA approval, a facility inspection is a major event. Notwithstanding the importance of the

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inspection and the issuance of a Form 483, Dendreon, Gold, and Urdal chose to conceal both the issuance of a Form 483 from the investing public and the "significant objectionable conditions" existing at Dendreon's New Jersey facility, aware that such an omission would result in the price of Dendreon's common stock being artificially inflated.

53. On March 1, 2007, Dendreon issued a press release discussing Dendreon's progress with respect to FDA approval. The press release mentioned numerous facts related to the progress of the application, but made no mention of the inspection or the issuance of a Form 483.

54. On March 2, 2007, Dendreon held a special telephonic meeting of its board of directors, in which Gold and Urdal participated. The minutes of the meeting reported:

> Dr. Urdal reported that the inspection was conducted by 5 FDA inspectors who informed the Company that the top three 483 issues regarding the manufacturing facility were: the Company's ability to do 12 lots concurrently; whether the Company will have the resources and staff to produce Provenge commercially; and establishing a clear chain of identity for the product in the form of bar coding.

55. Dendreon's 2006 Form 10-K ("2006 Form 10-K"), filed March 14, 2007, also omitted any mention of the fact of inspection, the conditions at Dendreon's manufacturing facility, or the issuance of a Form 483. In the 2006 Form 10-K, defendants also made various statements implying that "no audit or inspection [had] identifie[d] a failure to comply with applicable regulations" and that the FDA had not required Dendreon to take remedial measures.[6] The Company's March 14, 2007, Form 8-K and press release, which contained a section listing "Recent Highlights," also failed to disclose the FDA inspection of the Company's New Jersey facilities and the issuance of the Form 483. Failure to disclose that an inspection had taken

[6] *See* 2006 Form 10-K ("Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of FDA approval of Provenge or any of our other potential products.… If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming.…").

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place, which resulted in a Form 483 issued upon its completion, was a material omission from both the 2006 Form 10-K and the March 14, 2007, Form 8-K and press release.

56. The Form 10-K was materially misleading because it used future conditional language when, in fact, however, a Form 483 already had been issued that required remedial action. After the inspection, Urdal had his staff mobilize quickly to "evaluate the observations and to formulate an action plan in response to each." Thus, Urdal's team submitted "comprehensive responses" to the FDA on March 2, 2007.

57. Thereafter, the CMC reviewers at the FDA requested additional information from Dendreon in both March and April 2007. Although certain questions were resolved to the FDA's satisfaction, others were not. By March 23, 2007, it was clear that one of the inspection items, Observation No. 1, could not be resolved without a major amendment to the BLA. According to the notes of Mary Coon ("Coon"), Dendreon's Vice President of Quality, the Company held a conference call with the FDA on March 23, 2007. During the conference call, as Coon and Elizabeth Smith, Dendreon's Vice President of Regulatory Affairs, and Urdal have declared under oath, Dr. Keith Wonnacott, the FDA's lead product reviewer for Provenge, stated that the FDA wanted to inform the Company that because one of Dendreon's initial responses to the Form 483 observations included the submission of additional data, the FDA would consider it to be a major amendment that would push back the PDUFA date. During the teleconference with the FDA that day, in which defendant Urdal participated, Dendreon asked whether the FDA could grant a limited approval instead. Although the FDA agreed to consider the request, according to the FDA's record of the conference call, the FDA informed Dendreon that the proposal needed to be discussed internally before that could happen and that another discussion would not take place until after the Advisory Committee meeting on March 29, 2007. Thus, the FDA did not provide any assurances to Dendreon during the March 23, 2007, telephone conference that the inspection issues could be resolved in time for Provenge to be approved by the PDUFA date.

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58. On March 29, 2007, the FDA's Cellular, Tissue and Gene Therapies Advisory Committee was scheduled to issue its recommendations regarding Provenge. In anticipation of the recommendations, a hold was placed on the trading of Dendreon stock. At the close of trading on March 28, 2007 – the day before the announcement – Dendreon's share price was $5.22.

59. As planned, the Advisory Committee announced its recommendations on March 29, 2007. The Committee voted 17-0 that Provenge was reasonably safe, and 13-4 that the trial data showed substantial evidence that it was effective. That same day, Dendreon issued a press release announcing the Advisory Committee's recommendations. Again, the press release did not mention the FDA's CMC inspection, the issuance of the Form 483, or the possibility that the BLA application would have to be amended, causing the approval decision to be delayed by a number of months.

60. On March 29, 2007, after the FDA Advisory Committee announced its recommendations, Dendreon held an analyst conference call, during which the following exchange occurred:

> Analyst: Okay. Then final question with regard to time lines do you anticipate having to submit any additional information with regard to kind of the validation of your manufacturing processes?
>
> Defendant Gold: Sure. One of the things that we did as part of our biologic license application with the FDA, in particular the CMC section, was submit a lot of manufacturing data. As part of that, the FDA came out and we hosted them for preapproval inspections at our Hanover, New Jersey, facility.
>
> Analyst: Okay, and those facilities obviously passed the muster? Or, you know, can you give us more insight?
>
> Defendant Urdal: Actually, those are activities that we'll be discussing with the agency between now and the PDUFA date, so it's actually, we hosted a good inspection, I think, and we have ongoing discussions with them between now and between May 15 to finish the review of the CMC section.

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61. This announcement was the first time Dendreon had publicly disclosed information regarding the FDA's inspection. Interpreting Dendreon's failure to previously announce anything regarding the inspection and Gold's failure to elaborate on the outcome of the inspection to mean that there were no issues, the analyst responded: "Okay. Those facilities obviously passed the muster, or can you give us more insight?" The investment community paid close attention to Dendreon's capacity to produce Provenge because the Company emphasized that its ability to meet commercial-scale demands for the product would be a critical element for its success. Indeed, when Dendreon announced in April 2006 that its New Jersey facility would only have 12 workstations – a reduction from 48 originally planned – analysts and investors were alarmed by the reduction in capacity.

62. Defendant Urdal did not believe that Dendreon had hosted a "good inspection." Moreover, regardless of whether or not Urdal personally believed his statement to be true, his statement was nonetheless made with the knowledge and intent that it would mislead investors. Urdal was unquestionably in possession of facts that he knew would lead reasonable persons to reach the conclusion that it was not in fact a "good inspection." Despite being directly asked whether the facilities "passed muster," he deliberately omitted those negative facts from his response. Instead, he made a statement that was clearly designed to – and did – convey the materially false and misleading impression that the facilities had indeed "passed muster" (which they had not), and to cover up the existence of the Form 483, which he knew if disclosed to investors would lead them to conclude that it was not a "good inspection." Urdal's statement was therefore objectively and subjectively false and misleading.

63. A reasonable person would not have characterized an inspection that identified multiple "significant objectionable conditions" that were so severe they could not be resolved between mid-February and May 8, 2007 – when the FDA cited those issues as the first reason for denying the Provenge BLA – as a "good inspection." Defendant Urdal never described the "problems," "objectionable conditions," or "Form 483" during the conference call, despite the

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analyst's direct question of whether Dendreon's facilities "passed the muster." Urdal's avoidance of any mention of the FDA's notice of observations strongly suggests that he realized that investors would assess such problems as serious impediments to any approval within the six weeks remaining to the PDUFA date. Moreover, Urdal knew that with respect to one unresolved inspection issue, although the FDA was considering Dendreon's request for limited approval, rather than requiring a major amendment to the BLA that would postpone the May 15, 2007, PDUFA date, the FDA had not yet agreed to it.

64. Additionally, defendant Urdal's reference to "ongoing discussions … to finish the review of the CMC section" did not cause a reasonable investor to suspect that the FDA issued a Form 483 to Dendreon identifying multiple significant objectionable conditions at Dendreon's facilities. Indeed, there are several other aspects of the CMC review, such as discussions of labeling, that are completely independent of the pre-approval inspection. In choosing the words "*finish* the review," Defendant Urdal inaccurately implied that no ongoing issues relating to the pre-license inspection remained, and that completion involved discussion of these other issues. Because the FDA had not yet agreed to Dendreon's March 23, 2007, proposal for a limited approval in response to Observation No. 1 in the Form 483, there was a substantial likelihood that a major amendment would be required that would postpone the May 15, 2007, PDUFA date.

65. Moments after Urdal made his false and misleading statement regarding the inspection, Gold assured analysts and investors that Dendreon had always kept, and would continue to keep, the investment community informed of any developments concerning the Provenge BLA: "I think the Company has always taken it very much to heart that we want to keep the investment community up to speed and up to date on the information, so as we learn more from the FDA in our discussions with them, we'll let you know."

66. During the March 29, 2007, conference call, defendant Gold stated that "over the next *several weeks* we'll be *finalizing our discussions with the FDA* and we anticipate a decision on Provenge by May 15." Minutes later, Gold again stated that "[r]eally over the next several

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weeks, we're working on *completing* our discussions with the FDA and anticipate a decision on Provenge by May 15, 2007." These statements are materially misleading for the same reasons as Urdal's statement concerning finishing the CMC review.

67. Gold and Urdal were present during the entire conference call on March 29 with securities analysts and investors and they were both active participants on the call. Gold heard Urdal make his misleading "good inspection" and "finish the review of the CMC" statement. Indeed, Gold was the person to whom the analyst asked the question regarding whether Dendreon's facilities had "passed muster." As Dendreon's CEO and most senior officer, Gold had a legal duty to correct false and misleading statements made in his presence during an investor presentation. Despite having knowledge of the Form 483 and the significant objectionable conditions cited, Gold failed to correct or qualify Urdal's statement. Similarly, Urdal heard Gold make his statements that defendants always took "very much to heart" keeping the investment community "up to speed" on information obtained from the FDA and would continue to do so and that Dendreon would be finalizing the CMC review process within the next several weeks, in time for a May 15, 2007, determination on Provenge. As a Senior Vice President and Chief Scientific Officer of Dendreon, having been a participant in the March 23, 2007, conference call with the FDA, and despite having knowledge of the Form 483 and the significant objectionable conditions cited, Urdal failed to correct or qualify Gold's statements.

68. None of the analysts attending the telephone conference call on March 29 interpreted Urdal's or Gold's comments to mean that a Form 483 had been issued to Dendreon or that there were significant objectionable conditions at Dendreon's New Jersey facility. To the contrary, on March 30, 2007, Needham & Company, an established industry analyst firm, reported that, "At the conference call, management noted that the CMC review is moving along." The manner in which Urdal interrupted Gold and interjected himself into the exchange gives rise to a strong inference of scienter. Similarly, the fact that Gold falsely claimed to be forthcoming with respect to information obtained from the FDA and twice stressed that the CMC review

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process would be completed within the next few weeks also gives rise to a strong inference of scienter.

69. The market price of Dendreon's stock skyrocketed dramatically the next day, opening at $17.92 per share on March 30, 2007, a 343% increase over the March 28th closing price, and closed at $12.93 per share, a 247% increase over the March 28th closing price. Over 92 million shares of Dendreon stock were traded on March 30, 2007. With the exception of the week of March 26, 2007, trading volume in the prior three months exceeded 3 million shares only ten times, on no day exceeding 10 million shares.

70. On April 2, 2007, defendant Gold exercised options for thousands of shares of Dendreon common stock, at exercise prices between $2.21 and $5.45 per share, and then immediately sold 202,090 shares of Dendreon at $13.46, for approximately $2.7 million. These shares represented approximately 24% of his stock ownership. In conducting this transaction, Gold did not disclose the issuance of the Form 483 or any of the details regarding the "significant objectionable conditions" identified by FDA inspectors. Gold had been Dendreon's CEO since January 1, 2003. The April 2, 2007, sale was his first and only sale of Dendreon stock to date. Thus, this sale was dramatically out of line with his prior stock-trading history. Gold's sale was irregular, and raised red flags before the FDA even issued the Complete Response letter. One popular television financial commentator suggested shortly after Gold's stock sales (and before the Complete Response letter was published) that Gold's sales "left a bad taste in [his] mouth."

71. On April 4, 2007, representatives of the FDA and Dendreon conducted a teleconference to discuss Dendreon's response to the Form 483. Defendant Urdal was one of Dendreon's participants in the conference. As to four of the nine observations, Dendreon's responses were deemed adequate; two required submission of revised Standard Operating Procedures ("SOPs"), which Dendreon agreed to do. The remaining three items could not be resolved that day. Additional information in five areas was requested with respect to

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Observation No. 4, concerning proper production management and timing. Regarding Observation No. 3, the tracking of samples in the Quality Control laboratory, there was apparently some confusion in the submission. Dendreon was asked to provide five new additional pieces of information and told that after the information was provided, the FDA might have additional comments.

72. The most problematic item discussed on April 4, 2007, was Observation No. 1, which, if unresolved, would require a major amendment. According to the FDA, this would extend the PDUFA date. In response to Dendreon's earlier request, during the March 23, 2007, teleconference, the FDA made a proposal which could avoid that delay. While Dendreon generally agreed to the proposal, the Company suggested a modification and indicated that it would submit additional supporting data later in the week. The FDA indicated that Dendreon's counter-proposal "seemed problematic," but that it would consider the proposal.

73. Reflecting the serious nature of the FDA's observations, Urdal responded to a question by pharmaceutical company Pfizer during a conference call on April 12, 2007, by stating that "DNDN had 9 483's, 6 are minor, 3 are major and deal with capacity issues."

74. During the Relevant Period, Dendreon was one of the most actively-traded stocks on NASDAQ, trading in excess of 30 million shares (average) per day before the FDA's decision was announced. Dendreon's stock price reached its highest close in months, $23.58, on April 9, 2007.

75. As the PDUFA date drew nearer, it became clear to defendants that Provenge would not be approved by the PDUFA date as the Form 483 issues had not been resolved. Notwithstanding this knowledge and defendants' prior assurances that it would keep investors informed of the status of the application, defendants failed to inform investors of the status of the Provenge BLA or to make any disclosures about the Form 483. Defendants also failed to correct Urdal's statement that Dendreon had "hosted a good inspection" in February 2007 – a statement that was false and misleading when made – or both Urdal's and Gold's statements that the CMC

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process would be finalized within "several" weeks. By mid- to late-April, defendants knew that this was not the case.

76. On May 8, 2007, the FDA issued its Complete Response Letter to the Provenge BLA. Although the precise contents of the letter were not made public at the time, according to Dendreon's May 9, 2007 press release (which was incorporated into a Form 8-K filing with the SEC):

> The FDA has requested additional clinical data in support of the efficacy claim contained in the BLA. The Company is seeking a clarification from the FDA as to the nature of the data that is being requested. The FDA has also requested additional information with respect to the chemistry, manufacturing and controls (CMC) section of the BLA, which the Company believes it can supply to the FDA in a timely manner.

The now-public May 8, 2007, CR Letter listed as the very first deficiency: "Outstanding issues from your pre-license inspection, dated February 12-16, 2007, have yet to be resolved." The FDA later explained the bases for the initial CR Letter as follows: "The deficiencies included the absence of sufficient information to determine that the product would be safe and effective, as well as sufficient information to determine that the facility in which the product is manufactured, processed, packed or held would ensure the continued safety, purity, and potency of the product. Without this information, FDA could not make an approval determination."

77. On May 8, 2007, prior to the FDA action, Dendreon shares closed at $17.74. On May 9, 2007, after the disclosure of the CMC and efficacy issues, Dendreon's stock price plummeted to $6.33, causing substantial losses to plaintiff. Separate and apart from the efficacy issues, the CMC issues alone would have dashed Provenge's chances for approval. The FDA's records indicate that the CMC review team had independently concluded that "several product manufacturing and control items needed to be resolved" and had determined to issue a CR Letter.

78. On May 10, 2007, several Dendreon officers participated in a conference call with investors. During that call, Urdal, speaking on behalf of the Company, revealed the issuance of a Form 483 for the first time:

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> As you go through the license application review, there's a part of the review which involves the chemistry manufacturing control part – division of the FDA inspecting your facility.
>
> And we hosted a facility inspection by the FDA on the week of February 12th. And out of that inspection got several observations that were made that we've already been addressing quite effectively we think.
>
> And so, one of the items mentioned in the letter, for example, was just a reminder that we needed to complete our response to all the 483 items that came in that inspection. So, they're all observations that were made that we think we have well in hand, that none of the issues are ones that will delay the approval process from a manufacturing point of view.

79. This statement is notable for several reasons. First, Urdal acknowledged that the issues cited by the FDA in the CR Letter are the same as those identified in the Form 483 issued almost three months earlier. Second, he admitted that there were multiple "observations" (i.e., multiple "significant objectionable conditions"). Third, he indicated that Dendreon had not even completed its response to certain issues at the time that the FDA issued its CR Letter.

80. Urdal's attempts to downplay the significance of the CMC issues also reveal his lack of veracity and provide circumstantial evidence of scienter. Urdal's statement that the CMC issues could not delay the approval process is plainly false: the Provenge BLA could not be approved until Dendreon passed a pre-approval inspection. And, under Section 351 of the Public Health Safety Act, it is unlawful to introduce biologics into commerce from an unapproved facility. Thus, Urdal's assertion that the CMC issues could not delay approval had absolutely no basis in fact or law. Provenge would not be approved until the CMC issues were resolved, and even then, the Company would have to resubmit the BLA, which is a two- to six-month process. Further, as previously noted, there were no assurances that the FDA would not find other objectionable conditions in any reinspection during a new review cycle even if the initial objectionable conditions were resolved.

81. Urdal was then asked, "[c]an you give us a sense of the number of observations, or what kind of observations have been noted?" Gold interjected, "I think those are proprietary

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to the Company, Greg. I think as David said, there are things and the FDA has agreed with this in preliminary calls since we received the letter that these are things that we can easily address. These aren't big issues, but we wanted the investment community to know that they were included in the letter."

82. Gold was not telling the truth, either on March 29, 2007, or on May 10, 2007, about the Company's purported desire to keep the investment community informed about the progress of the approval process. FDA records reveal that during a teleconference with FDA representatives on May 9, 2007, Gold raised the subject of confidentiality. Specifically, Gold asked the FDA if there was a chance the CR Letter would be leaked to the press. The FDA indicated that the CR Letter would not be made public, nor would the FDA release any public statement on the matter.

83. Gold's efforts to conceal the facts surrounding the Form 483 also make it reasonable to infer that the issues noted by the FDA's inspectors were severe and that Gold was aware of his own wrongdoing – both at the March 29th conference call and in his subsequent sale of millions of dollars in stock. Indeed, the number of objectionable conditions and general nature of those conditions are not proprietary information.

84. Both Gold's and Urdal's portrayals of the CMC issues as minor are also inconsistent with the *fact* that Dendreon did not resolve the problems in the roughly three months after Dendreon received the Form 483, and the fact that Dendreon, as recently as March 13, 2008, more than one year after the inspection, had been unable to confirm that the issues originally identified in February 2007 had been resolved.

85. During the May 10, 2007 call, Gold stated that there had been "little interaction" between Dendreon and the FDA:

> I think what was surprising to us after the panel meeting was the very limited amount, if any, discussions that we had with the FDA. There was very little interaction between the Company and the Agency between the Panel Meeting and when we received the complete response letter.

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This comment suggests that the CR Letter denying approval was surprising, especially after panel approval had been granted. This comment was disingenuous. Dendreon representatives, including defendant Urdal, discussed the adequacy of Dendreon's response to the Form 483 on April 4, 2007 – after the March 29, 2007, Advisory Committee meeting – at which time specific information was requested and the parties exchanged ideas for potential resolution of Observation No. 1. The fact that the FDA did not contact Dendreon to assent to its proposal was a negative development for Dendreon. Consequently, the portrayal of any lack of contact as having been understood to be implicitly good news was not a candid assessment.

86. In subsequent investor conference calls, defendants, while continuing to downplay the significance of the Form 483 issues, were unable to confirm that they had been resolved. For example, during a March 13, 2008, conference call with securities analysts and investors, Gold acknowledged that Dendreon had still not yet fully resolved the CMC issues:

> Analyst: We had a couple of questions. Number one we were wondering where we stand with the CMC issue that was addressed in the CR Letter and then secondly we were curious about how the stopping boundaries were established in the IMPACT analysis and whether or not we are using a group sequential method?
>
> Gold: Joe, what was your first question again?
>
> Analyst: Where do we stand on the CMC, on the CR Letter?
>
> Gold: The CMC issues that were raised during the pre-approval inspection Dendreon has substantially responded to – you have an echo on your phone there. If you're on speaker phone I'd ask you to take it off.

87. During the Relevant Period, neither the fact of inspection nor the issuance of the Form 483 was made public by any source outside of Dendreon. Forms 483 are not publicly available, and they are required to be treated as confidential by the FDA until disclosed by the applicant.

88. Dendreon's stock price would have never risen as high as it did had the investing public known that the FDA had raised CMC concerns and that the FDA had issued a Form 483.

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Defendants' course of conduct operated as a fraud on purchasers of Dendreon's common stock, deceived the investing public regarding the likelihood and timing of FDA approval of Provenge, and artificially inflated the price of Dendreon's common stock. Defendants' conduct also caused Plaintiff to purchase Dendreon's publicly traded securities at artificially inflated prices, and caused Plaintiff substantial loss when both the fact and consequence of the concealed information was made public.

V. FRAUD ON THE MARKET ALLEGATIONS

89. At all relevant times, the market for Dendreon stock was open, well-developed, and efficient. As a result of the materially false and misleading statements and omissions alleged herein, Dendreon securities traded at artificially inflated prices during the Relevant Period. Plaintiff purchased or otherwise acquired Dendreon securities relying upon the integrity of the market price for Dendreon securities and market information relating to the Company, and has been damaged thereby. At all relevant times, the material misrepresentations and omissions alleged herein directly or proximately caused, or were a substantial contributing cause, of the damages sustained by plaintiff. The material misstatements and omissions described herein had the cause and effect of creating in the market an unrealistically positive assessment of Dendreon and its business and operations, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. The Individual Defendants' materially false and misleading statements during the Relevant Period resulted in plaintiff purchasing or acquiring the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

90. Additionally, the market for the Company's stock was efficient for the following reasons, among others:

(a) Dendreon's stock met the requirements for listing, and was listed and actively traded on the Nasdaq National Market System, a highly efficient and automated market;

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(b) As a regulated issuer, Dendreon filed periodic public reports with the SEC; and

(c) Dendreon regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wideranging public disclosures, such a communications with the financial press and other similar reporting services.

91. As a result of the foregoing, the market for Dendreon's stock promptly digested current information regarding Dendreon from all publicly-available sources and reflected such information in Dendreon's stock price; thus, a presumption of reliance upon defendants' material misstatements and omissions applies.

92. In particular, the market was focused upon any information bearing upon the timing of the FDA's decision concerning approval of Provenge. For example, on March 1, 2007, the same day as Dendreon issued a positive press release announcing the progress of the BLA, including that the application had been granted "Priority Review" status, affording Dendreon a decision on Provenge by May 15, 2007, and that, in conjunction therewith, the Cellular, Tissue and Gene Therapies Advisory Committee would review the BLA on March 29, 2007, one analyst following the stock, Jonathan Aschoff of Brean Murray, Carret & Co., rated Dendreon a "sell," and established a mere $1.50 target price.

93. Citing the fact that both of Provenge's Phase 3 trials "failed their primary endpoints and instead used the second median survival endpoint," Aschoff indicated that it was unlikely that Provenge would be approved outright by the FDA in May, and that the "best-case" scenario would instead be the issuance of an "approvable" letter, contingent upon the results of further trials, due to be completed in the second half of 2008. Aschoff went as far as to predict that Provenge would ultimately fail in that test trial. Noting the market's negative reaction to that analyst report, Bloomberg also reported, after the close on March 1, 2007, that Dendreon's short interest had been rising since October as more investors are betting against approval. That

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day, Dendreon's share price tumbled almost 9%, from $4.64 to $4.23, on a trading volume four times higher than the average over the past three months.

94. Following Advisory Committee approval on March 29, 2007, because of the significant controversy surrounding the panel's efficacy finding, passed on a 13-4 vote, Dendreon's stock price during the Relevant Period continued to reflect the uncertainty of FDA approval for Provenge. For example, although defendants were bullish on approval by the PDUFA date during the March 29, 2007, conference call, as noted by the analyst from Needham & Company, on March 30, 2007, Bloomberg reported: "After the vote, UBS maintained its position that Dendreon is unlikely to get a speedy FDA approval because of cautious comments from the panel, according to a note to clients by analyst Graig Suvannavejh." Despite the existence of such negative commentary, the panel approval decision was generally well-received and initially buoyed Dendreon's share price in the ensuing weeks.

95. After Dendreon's highest close in months, $23.58 on April 9, 2007, Dendreon hit an intra-day trading price of $25.25 on April 10, 2007. Thereafter, a chorus of naysayers began to hold sway over investors. An April 10, 2007, Seeking Alpha article entitled, "Dendreon: Don't Forget About Risk vs. Reward," mirrored the criticism of Dendreon's data first raised by Jonathan Aschoff. The author noted: "While I acknowledge the FDA typically follows the panel's recommendation, I would find it surprising if the FDA did so in this case. In the past, the FDA has rejected drugs that did not meet its primary endpoints. Based on two small trials which failed to meet its primary endpoint, and a post analysis result that was not replicated in the following trial, it would be 'out of character' for the FDA to approve Provenge on May 15." Also noting that the FDA will likely hinge approval on the results of ongoing trials not due for completion until 2008 and beyond, the author concluded: "I question whether the risk/reward is worth it at the current stock price of $23-$24 having increased ~500% over the last 2 weeks for something that potentially may or may not come for another 3 years. While I'm cautiously

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optimistic on the approval process going forward, the stock price has gotten way ahead of itself given the likely scenario of the issuance of an approvable letter."

96. Also on April 10, 2007, analyst MDB Capital noted that it was not clear that the FDA would heed the recommendation of its advisory panel with respect to approval for Provenge. MDB stated: "The recent vote (13 to 4) in favor of Provenge approval by the cellular, tissue and gene therapy advisory panel was a surprise. We believe the FDA will think hard about this one and is probably in a dilemma of sorts. While the FDA normally heeds the decision of its advisory panel, this particular case may not be clear cut." As a result, MDB maintained a "neutral" rating on Dendreon.

97. On April 11, 2007, Charles Duncan of JMP Securities ("JMP"), another analyst firm covering Dendreon, issued a note downgrading the Company's stock, from "strong buy" to "market outperform," citing only a 50% probability that Provenge would be granted full approval by the FDA by the Prescription Drug User Fee Act date.

98. Duncan's comments were reported on Forbes.com. Also on April 11, 2007, investment bank Leerink Swann held a conference call for clients during which the participants were strongly negative about Dendreon's chances of FDA approval for Provenge. Specifically, Leerink Swann presented three regulatory experts to discuss Provenge and all predicted confidently that the FDA would not approve Provenge by the May 15th deadline. By market close, Dendreon's price had dropped to $18.23, more than $7 less than the intra-day trading high on April 10, 2007.

99. On April 12, 2007, Dendreon's stock continued to fall after Brean Murray reiterated its "strong sell" rating, closing at $18.01.

100. On April 13, 2007, *The Cancer Letter*, a weekly oncology paper, published a letter to the FDA from Dr. Howard Scher, a prominent urological oncologist from Sloan-Kettering Memorial Cancer Center and a member of the Oncology Drugs Advisory Committee.

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Dr. Scher, who sat on the Provenge review panel, and voted against Provenge on the question of substantial efficacy, wrote the following:

> I am writing to express concerns about the recent review of Sipuleucel-T at the FDA Advisory Meeting on March 29, 2007. These concerns are: a recommendation for approval based on data that fall short of the regulatory requirements; an inadequate statistical construct to determine definitive benefit; incomplete data on product safety; and what appear to be different criteria for approval by two Advisory Committees to the Agency. All but the latter were discussed in the open meeting, but warrant further consideration given the outcome. The concerns are based on my experience as a voting member on several ODACs representing the Agency, and separately, as a Presenter to ODAC for Industry Sponsors. I have been one of the Academic Leaders of the Prostate Cancer Clinical Trial Endpoints initiative begun under the joint Sponsorship of the FDA, AACR, ASCO and PCF in 2004, which were presented at the February 2007, Prostate ASCO Meeting in Orlando.
>
> * * *
>
> Let me state at the outset that I was one of the four Committee Members who voted "no" to the question whether the trials presented by the Sponsor established the efficacy or demonstrated substantial evidence of benefit to justify an approval recommendation to the FDA. My vote was based on the fact that neither of the two trials presented met their primary endpoint, which renders the significance of results from any subsequent analyses as "exploratory" and "hypothesis generating." As such, the results do not constitute "proof" of benefit or justify a conclusion that they are "reasonably likely" to predict benefit. The trial data were not consistent. Even if one accepts the post hoc survival analysis results of the larger 127 patient trial (82 men treated with Sipuleucel-T and 45 men treated with a "placebo"), the second trial of 98 patients (65 treated with Sipuleucel-T and 33 with placebo) was not confirmatory. Consequently, the only conclusion that can be reached is that the survival difference observed may have occurred by chance alone, and that the results do not support an approval recommendation. This, and the Sponsor's recognition that an additional prospective study was needed, mandates deferring any decision on whether an approval should be granted until the results of the ongoing 500 patient phase 3 trial that is powered on a primary endpoint of survival, is accrued and analyzed.
>
> Concerns about the validity of the findings were reinforced by the absence of other signals of an antitumor effect. Specifically there were no data provided of a favorable effect on PSA, regression or stabilization of soft-tissue or boney disease radiographically, health

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> related quality of life, or that administration of the product delayed the development of pain. Even the time to the administration of chemotherapy, an indication to the treating Physicians that the clinical course had worsened, was similar between the two groups. Reinforcing the uncertainty was the fact that in response to a direct question at the meeting, none of the Physicians representing the Sponsor could articulate how treatment with the product had "helped" any individual patient.
>
> * * *
>
> Finally, the original question posed by the Agency to the Advisory Committee at the meeting was: "Does the submitted data establish the efficacy of Sipuleucel-T (APC-8015) in the intended population?" The first 4 respondees on the Committee voted "no." The question was then changed to: Do the data show "substantial evidence." A series of "yes" votes followed. Consider the conclusion in the manuscript describing the results of trial 9901, published in the Journal of Clinical Oncology in Volume 24, page 3093, in 2006.(JCO 24:3089, 2006). In it, the Investigators state "that while sipuleucel-T fell short of demonstrating a statistically significant difference in TTP, it MAY provide a survival advantage to asymptomatic HRPC patients. Supportive studies are underway to confirm this effect." All of the difficulties cited, and the Investigator's own conclusions, show how there are simply too many alternative explanations for the observed survival difference beyond treatment with Sipuleucel-T. Couple this with that fact that were no secondary signals of an antitumor effect and no confirmatory trial however flawed, mandates that any decision for approval be deferred until the phase 3 study, currently underway, has been completed and analyzed.

101. On Monday, April 16, 2007, the first trading day after Dr. Scher's letter to the FDA was made public, Brean Murray reported that Dr. Scher's letter to the FDA – analyzing the Provenge test-trial data and concluding that it "mandates" deferral of approval – "confirms our bearish thesis" about Dendreon. Upon the news of Dr. Scher's critical letter to the FDA, Dendreon's price sharply declined from the April 13, 2007, close of $17.25 to $15.72.

102. Also suspicious of approval, an April 20, 2007, Forbes article entitled, "The Danger in Dendreon" reported the following:

> The FDA has a legal deadline of May 15 to make a decision – although it is possible to break or extend it. But buying the stock in front of this deadline is probably highly risky. There is a reasonable chance the FDA will decide to go against the panel vote and ask for more data. And the downside to the stock if the FDA

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does delay approval by asking Dendreon for more data is probably much bigger than any potential gain.

Why? For one thing, an approval might be priced in. Two years ago, Geoffrey Porges, an analyst at Sanford C. Bernstein, analyzed the likely performance of biotech stocks following FDA decisions. Some 70% of the time, Porges found, drugs were approved, and shares in their makers gradually rose. But when a drug failed, stocks cratered 40%. The net result is that betting that drugs are going to get approved is a good way to lose money. In contrast, if you shorted stocks before FDA decisions, you'd make money.

Another problem is that the FDA is much less likely to follow the whims of its advisory committees than many investors seem to think. The agency does follow the advice of these committees most of the time, but there are plenty of reasons to believe Dendreon might be an exception.

Dendreon's application to the FDA contains two late-stage studies with a combined total of 225 patients. That's tiny; many drugs are tested in studies of thousands of patients. Both studies missed their main goal, but the more recent one – a three-year, 124-patient study – shows that patients on the drug lived, on average, an extra four months.

But statisticians, and the FDA, tend to toss out studies that don't make their main goal. To cancer patients, this can sound insensitive. But there's a real reason for it. When a study gives a result that scientists didn't predict ahead of time, it's simply more likely that the result happened by chance.

The panel did weigh those risks, and it still recommended Provenge by a 13-4 vote. One study shows that when an FDA panel recommends approval, the FDA will approve the drug 97% of the time. Both a concerned investor and Dendreon's outside public relations firm point to this research, conducted by the National Research Center for Women & Families.

That statistic is misleading, though, because the study counts approvals that happened months or years after the panel voted. Nobody expects the FDA to reject Provenge outright. Instead, the FDA would probably grant an "approvable letter," basically saying it will approve the drug if certain conditions are met. Dendreon is already conducting a 500-patient study that will give a much clearer answer as to whether Provenge works. If the drug is approved, it may make it difficult to conduct that placebo-controlled trial.

Also, the NRCWF report basically argues that the FDA approves drugs too often. It is exactly the kind of criticism that could lead to the agency becoming more reticent. And it picked committees at

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> random, missing the advisory committee for cancer drugs, where a lot of controversies happen. Also, it doesn't include two cases where the FDA did go against a committee.
>
> An advisory committee recommended that *Merck*'s (nyse: MRK - news - people) Vioxx be put back on the market; the FDA found a way to not bring it back without actually contradicting the committee's recommendation. And a committee recommended approval for Pargluva, a diabetes drug from *Bristol-Myers Squibb* (nyse: BMY - news - people). After safety issues emerged, the FDA asked for a large study, basically killing the drug's chances.
>
> If the agency wants to ask Dendreon for more data, it certainly has some outs. The FDA changed the wording of a question during the panel, so instead of just saying Provenge should be approved, it said there was substantial evidence for its efficacy. Also, the panel that looked at Provenge was the one for cellular, tissue and gene therapies, not the panel that normally deals with cancer drugs.
>
> Richard Pazdur, head of the Office of Oncology Drug Products, has set a high bar for judging the effectiveness of cancer drugs. His office is completely removed from the one that convened the Provenge panel.
>
> Many of the panelists on the cellular, tissue and gene therapies panel were researchers, not doctors who treat patients. One of the "no" votes was Howard Scher, of the Memorial Sloan-Kettering Cancer Center, who has made a career of designing trials to test prostate cancer drugs. The Cancer Letter, an industry newsletter, obtained a confidential letter Scher sent to the FDA arguing that Provenge should not be approved. Memorial Sloan-Kettering says that Scher had nothing to do with making the letter public.
>
> In the letter, Scher voices four concerns: The recommendation to approve fell short of regulatory requirements; the statistics are "inadequate" to determine whether patients were helped; the data on safety are incomplete; and the advisory committee seemed to be using a different set of criteria compared to those for other cancer drugs.
>
> The panel vote does make an approval more likely. But the FDA can go against its panels, and it has in the past. There are plenty of reasons to delay approval until a big safety study emerges. And the pain of a rejection could be worse than the pleasure of approval. Until Dendreon gets a fax from the FDA, what happens next is anybody's guess.

103. On April 23, 2007, in an article on Seeking Alpha entitled, "Dendreon: Revisiting the Risk/Reward Scenario," the author wrote: "[i]nvestor sentiment has flipped from expecting

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an approval to expecting an approvable letter. Subsequently, the stock price has decreased 40% from its highs."

104. On April 26, 2007, the Company's stock weakened further upon the publication of an article on Forbes.com entitled "Doctor Voices Dendreon Doubts." The article stated that *The Cancer Letter* reported that *second* panel member who had voted against approval of Provenge, Dr. Maha Hussein, also wrote the FDA to urge against approval of Provenge. Dendreon's stock price dropped $1.35, from $16.80 to $15.45, with more than 20 million shares trading hands.

105. After shooting up $20, to as high as $25.25, in the first ten days following panel approval, between April 11, 2007, and May 8, 2007, as serious doubts about Provenge's efficacy were repeatedly raised, Dendreon's shares traded in the low $15 to low $18 range, only once rising above $19 per share.

106. In stark contrast to the open and frank discussion concerning the growing likelihood that the FDA would not grant full approval, based upon failures of two studies to achieve their endpoints, *investors were not aware of any of the "major" CMC problems that Dendreon was experiencing because of the unresolved Form 483 issues*. Thus, the FDA's failure to approve Provenge based upon efficacy grounds was anticipated by many investors and already incorporated, in part, in Dendreon's price; in contrast, the material news that approval was also denied on the independent basis that significant CMC issues noted during the mid-February inspection remained unresolved had not yet been reflected in Dendreon's share price prior to the announcement on May 9, 2007, that the FDA had issued an "approvable" letter.

VI. NO SAFE HARBOR

107. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false and misleading statements alleged in this complaint. Specifically, Urdal's characterization of the inspection and defendants' other false and misleading statements concerned presently existing facts rather than future events and were

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therefore not forward-looking statements. Additionally, many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements plead herein, the Individual Defendants are liable for those forward-looking statements because at the time each of those forward-looking statements were made, the particular speaker had actual knowledge that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that such statements were false when made.

FIRST CLAIM FOR RELIEF

(FOR VIOLATIONS OF § 10(B) OF THE EXCHANGE ACT AND SEC RULE 10B-5 AGAINST ALL DEFENDANTS)

108. Plaintiff incorporates by reference each of the preceding paragraphs as though they were set forth in full herein.

109. Throughout the Relevant Period, defendants individually and in concert, directly and indirectly, by the use and means of instrumentalities of interstate commerce and/or of the mails, engaged and participated in a course of conduct to conceal adverse material information about Dendreon, including the fact of the FDA inspection, the issuance of a Form 483, the contents of that Form 483, and the potential delay of the PDUFA date because of one or more of the observations in the Form 483.

110. Defendants violated §10(b) of the Exchange Act and SEC Rule 10b-5 in that they, individually and in concert:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue or misleading statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and

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(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff in connection with its purchases of Dendreon common stock during the Relevant Period.

111. Gold and Urdal, as the top executive officers of the Company, are liable as direct participants in the wrongs complained of herein. With knowledge of the results of the FDA inspection and the "significant objectionable conditions" at Dendreon's New Jersey facility, Urdal falsely and misleadingly represented that Dendreon had hosted a "good inspection." This opinion was both objectively and subjectively false and misleading when made in that Urdal did not believe that Dendreon had "hosted a good inspection" and, even if he did, he knew that his statement would mislead investors.

112. With knowledge of the results of the FDA inspection and the "significant objectionable conditions" at Dendreon's New Jersey facility, and of the fact that the FDA had not yet decided to approve Dendreon's request for limited approval in lieu of a major amendment to the BLA application (to avoid a delay of the PDUFA date), both Urdal and Gold made specific comments indicating that the CMC review process would be timely completed prior to the PDUFA date.

113. Gold and Urdal deliberately failed to correct or qualify the other's respective false and misleading statements regarding the inspection and completion of CMC review, notwithstanding their knowledge of the results of the inspection, their knowledge that the statements would cause investors to believe that no significant problems had been identified during the inspection and/or that they would be resolved before the PDUFA date, and their knowledge that reasonable investors would reach a contrary conclusion if they knew about the existence of the Form 483 and the unresolved status of Dendreon's request for limited approval so as to retain the PDUFA date. Similarly, Urdal deliberately failed to correct or qualify Gold's statement indicating that defendants had timely provided and would continue to timely provide investors with information obtained from the FDA.

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114. The following non-exhaustive list of facts establishes a strong inference that defendant Urdal acted with the requisite scienter:

- Urdal was Dendreon's Chief Scientific Officer and the corporate officer responsible for Dendreon's New Jersey facility that was inspected in February 2007;
- Urdal received the Form 483, knew its contents, and knew that the issues cited therein were serious because: (a) a Form 483, by definition, only lists "significant objectionable conditions;" (b) the Form 483 issued to Dendreon listed multiple "significant objectionable conditions;" (c) Dendreon was unable to resolve, or even submit a remedial plan for, all the "significant objectionable conditions" identified by the FDA from mid-February to May 8, 2007, and had still not resolved those issues as of March 7, 2008;
- Urdal further knew that the FDA would "not approve [Provenge] unless the manufacturing facilities are in compliance with FDA's cGMP," see Dendreon 2006 Form 10-K;
- Urdal falsely stated that "we hosted a good inspection" and that Dendreon would timely "finish the review of the CMC" without mentioning the Form 483 or any of the numerous "significant objectionable conditions" identified by FDA inspectors;
- Urdal failed to correct or qualify Gold's statements concerning Dendreon's timely provision of information received from the FDA to investors or that the CMC review process would be "finalized" and "completed" within the next several weeks, such that the FDA could approve Provenge by the PDUFA date;
- Urdal's team prepared Dendreon's comprehensive response to the Form 483 on March 2, 2007, and Urdal discussed the observations contained in the Form 483 with the FDA on March 23, 2007, at which time it was discussed that a major amendment might be required with respect to Observation No. 1 which could delay the PDUFA date, and that Dendreon would not be informed of the FDA's decision until after March 29, 2007;
- Urdal participated in the April 4, 2007, teleconference with the FDA to discuss the response to the Form 483. Although six of the nine issues were resolved or could soon be, additional information was requested with respect to two observations (with follow up questions likely after receipt) and, with respect to Observation No. 1, the FDA did not agree to Dendreon's

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proposal for limited approval (to avoid delay of the PDUFA date) and its counter-proposal was termed "problematic;"

- As the PDUFA date grew nearer and it became clear from the lack of further discussions with the FDA and Dendreon's failure to submit a complete corrective action plan on all nine observations that it would not pass the CMC Review and the Provenge BLA would not be approved, Urdal continued to conceal the CMC issues and failed to correct his prior false statement that Dendreon had "hosted a good inspection;"

- After Dendreon received a Complete Response Letter citing the CMC issues identified during the inspection the first reason for denial, Urdal knowingly made numerous false statements concerning whether the CMC issues would have prevented approval. In suggesting that the CMC issues would not have delayed approval, Urdal contradicted his own private assessment of three of the issues as "major" when speaking to Pfizer on April 12, 2007, as well as Dendreon's own SEC filings and federal regulations; and

- To conceal his wrongdoing, Urdal steadfastly refused to disclose, even in broad details, the number and nature of the "significant objectionable conditions" identified by FDA inspectors in February 2007.

115. The following non-exhaustive list of facts establishes a strong inference that defendant Gold acted with the requisite scienter:

- Gold, as Dendreon's President and CEO, received the Form 483, knew its contents, and knew that the issues cited therein were serious because: (a) a Form 483, by definition, only lists "significant objectionable conditions;" (b) the Form 483 listed multiple "significant objectionable conditions; (c) Dendreon was unable to resolve, or even submit a remedial plan for, all the "significant objectionable conditions" from mid-February to May 8, and had still not resolved those issues as of March 7, 2008;

- Gold further knew that the FDA would "not approve [Provenge] unless the manufacturing facilities are in compliance with FDA's cGMP," see Dendreon 2006 Form 10-K;

- At the March 29, 2007, conference call, Gold mentioned the inspection without disclosing the outcome. Gold further made no effort to correct Urdal's statement that Dendreon had "hosted a good inspection" or to disclose the issuance of the Form 483 at the March 29 conference call. Gold also knew, but failed to disclose, that a rejection of Dendreon's

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outstanding request for limited approval with respect to Observation No. 1 would mean a delay of the PDUFA date;

- At the March 29, 2007 conference call, Gold twice misled investors by indicating that within several weeks Dendreon would complete the CMC review process, while omitting any reference to the outstanding Form 483 issues; he also misled investors by indicating that Dendreon took to heart its obligation to timely inform investors of new information obtained from the FDA and was acting accordingly;

- Days after failing to correct Urdal's false and misleading statement and making misleading statements of his own, and days before Dendreon's meeting with the FDA concerning the Form 483 – and with the existence of the Form 483 and significant objectionable conditions not publicly known – Gold proceeded to sell of almost a quarter of his Dendreon holdings for $2.7 million;

- After open issues remained following the April 4, 2007, teleconference with the FDA concerning the Form 483, and as the PDUFA date grew nearer and it became clear from the lack of further discussions with the FDA and Dendreon's failure to submit a complete corrective action plan, that the Provenge BLA would not be approved, Gold continued to conceal the CMC issues from investors and failed to correct Urdal's false statement that Dendreon had "hosted a good inspection" and both of their misleading statements concerning the timely completion of the CMC review process;

- Despite expressly stating that Dendreon would be forthcoming to investors with information received from the FDA, after Dendreon received a CR Letter citing the CMC inspection issues as the first reason for denial, Gold took actions to conceal Dendreon's wrongdoing from investors. Specifically, at the May 10, 2007, conference call, he made the astounding claim that the number of conditions identified by the FDA and their general nature were "proprietary" to the Company and could not be disclosed to investors. In fact, during a teleconference with the FDA on May 9, 2007, it was Gold who expressed concerns about confidentiality and asked the FDA if there was a chance the CR Letter would be leaked to the press; and

- Gold led investors and analysts to believe that there were few, if any, discussions with the FDA after Provenge received panel approval, suggesting that defendants were surprised by the CR Letter. In fact, defendants had discussed the Form 483 with the FDA six days after the Advisory Committee meeting wherein panel approval was granted, and a number of significant open issues remained after the call.

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Because both Gold and Urdal acted with the requisite scienter, scienter is established as to Dendreon.

116. Plaintiff has suffered damages in that, in reliance on the integrity of the market, it paid artificially inflated prices for Dendreon common stock. Plaintiff would not have purchased Dendreon common stock at the prices it paid, or at all, if it had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements and omissions. As a direct and proximate result of defendants' wrongful conduct, Plaintiff suffered damages in connection with its purchases of Dendreon common stock during the Relevant Period.

SECOND CLAIM FOR RELIEF

(FOR VIOLATIONS OF § 20(A) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS)

117. Plaintiff incorporates by reference each of the preceding paragraphs as though they were set forth in full herein.

118. Gold and Urdal were controlling persons of Dendreon within the meaning of §20(a) of the Exchange Act. By reason of their positions as officers and directors of Dendreon, and as to their ownership of Dendreon common stock, Gold and Urdal had the power and authority to cause, and exercised that power and authority to cause, Dendreon to engage in the wrongful conduct complained of herein. Furthermore, because of their positions within the Company, Gold and Urdal exercised day-to-day control over the Company and possessed the power and authority to control the contents of the statements made on behalf of the Company. By reason of such conduct, Gold and Urdal are liable to plaintiff pursuant to § 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Awarding plaintiff compensatory damages in an amount to be proven at trial, together with interest thereon;

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B. Awarding plaintiff interest and reasonable attorneys' fees pursuant to RCW § 21.20.430(1);

C. Awarding plaintiff pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, experts' witness fees, and other costs and disbursements; and

D. Awarding plaintiff such other relief as this Court may deem just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiff hereby demands a trial by jury of all issues so triable.

Dated: January 7, 2011

Respectfully submitted,

HAGENS BERMAN, LLP

/s/ Karl P. Barth

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